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Plan B Pill May Be Approaching Wider Release

Over-the-counter sale of the 'morning-after' contraceptive hinges on adult-only access.

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WASHINGTON — The Food and Drug Administration, in a surprise move that angered religious conservatives, offered a proposal Monday to allow the "morning-after" birth control pill to be sold without a prescription to women age 18 and older.

It marked a potentially significant step toward breaking the stalemate between people who worry that unrestricted access to the pill could encourage promiscuity, and people — including the FDA's medical staff — who say scientific evidence shows the drug is safe.

The proposal came in a letter from the FDA to Barr Pharmaceuticals Inc., manufacturer of the pill known as Plan B. Barr was asked to describe the steps it would take to prevent sales to customers younger than 18 if the agency approved over-the-counter sales for adults. The FDA said it wanted to make a final decision on distribution in a matter of weeks.

Plan B allows women to prevent pregnancy by taking a high dose of a conventional contraceptive hormone up to 72 hours after unprotected sex.

California and seven other states have circumvented the FDA by using their regulatory powers over pharmacies to make Plan B available without a prescription.

The letter, signed by acting FDA Commissioner Andrew C. von Eschenbach, was seen by some as a signal that the Bush administration was prepared to move forward with approval as recommended by its scientific staff more than two years ago.

FDA officials seem "inclined to approve it," said economist John E. Calfee, who follows the drug industry for the American Enterprise Institute, a business-oriented think tank. "They just want [the manufacturer] to say the right things about how they are going to monitor the use of the drug."

But critics, led by religious conservatives, made clear they had no intention of relaxing their opposition to wider release of Plan B.

"The FDA cannot find time to withdraw the dangerous abortion pill RU-486 from the market no matter how many women die after taking it, but now the rogue agency is

willing to reopen debate on whether to remove medical care from the morning-after pill," Concerned Women for America, a conservative Christian organization, said in a press release. "The prescription process protects women's health."

The FDA is investigating the cases of several women who used RU-486 and died from a rare type of infection.

Plan B is classified as a contraceptive, not an abortion drug like RU-486, which is taken to end an established pregnancy.

Planned Parenthood, which favors nonprescription status for Plan B, said in a statement that the announcement "holds the potential for improving women's health if the FDA keeps its word this time."

Von Eschenbach has a Senate confirmation hearing today. His nomination has been snared in the political controversy over FDA handling of the morning-after pill.

The FDA has determined that 18 is the "appropriate age" to allow women to buy Plan B without a prescription, Von Eschenbach's letter said, but the agency has questions about the practicality of the manufacturer's proposal to keep drugstores from selling it to minors. He requested a meeting with Barr representatives within seven days.

The battle over Plan B has jeopardized Von Eschenbach's future at the FDA at a time when many think the agency needs permanent leadership to keep up with rapid changes in its areas of responsibility and to resolve questions about its oversight of prescription safety.

A decision on Plan B has been pending since 2003. Two senators angry over delays said they would continue to block a floor vote on Von Eschenbach until the FDA made a firm ruling.

The FDA's announcement "is really a nondecision," said Sen. Patty Murray (D-Wash.), who with Sen. Hillary Rodham Clinton (D-N.Y.) is blocking the nomination.

Murray pointed out that as recently as last year, the Bush administration had promised a final decision, only to backpedal after a prior FDA commissioner won Senate confirmation. "Fool me once," she said. "We're not going to go there again. We will keep our hold on this nomination until we get a 'yes' or 'no' on Plan B."

But the drug's manufacturer saw a possible opening toward a resolution. "I think it's a positive development," Barr spokeswoman Carol Cox said Monday.

"Until we meet with them and go over what kinds of questions they have, it's probably premature to know what kinds of hurdles there might be," she added. Barr's stock rose about 2% on news of the FDA letter.

Health and Human Services Secretary Mike Leavitt said the letter from the FDA demonstrated "a good-faith effort on the part of Dr. Von Eschenbach to help resolve the issues surrounding Plan B."

On Capitol Hill, however, FDA pronouncements on Plan B have been met with skepticism. Last year, an extensive Government Accountability Office review of the FDA's handling of Plan B found that it had not followed its usual science-based process in making decisions.

Von Eschenbach's letter suggested that the decision would hinge on the manufacturer's plan for keeping Plan B out of the hands of minors.

"If after our discussions we conclude that [enforcement] isn't sufficiently rigorous to prevent … Plan B from being used by young girls who can't safely use the product without supervision," then it will remain a prescription-only drug, Von Eschenbach wrote.

Barr Pharmaceuticals already has proposed limiting over-the-counter sales to pharmacies that agree to keep the drug behind the counter and dispensing it only after a customer shows proof of age.

But Von Eschenbach said the FDA wanted more detail, particularly on whether those restrictions would be written into a formal contract that the manufacturer would enforce.

Wendy Wright, president of Concerned Women for America, said she did not see how such a restriction could be enforced.

"The person who buys the drug is not necessarily the person who will take the drug," she said. "What the FDA would have to consider is a foolproof plan to keep proxies from buying the drug and giving it to adolescents."

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(INFOBOX BELOW)

Plan B pill

Morning-after pills are considered "emergency contraception," with higher doses of the hormones present in regular birth control pills. Unlike abortion pill RU-486, morning-after pills are not intended to end an established pregnancy.

How Plan B works

First dose is taken within 72 hours of unprotected sex. Second dose is taken 12 hours later. Pregnancy may be prevented in the following ways:

1. The ovary can delay an egg's release

2. Fertilization may be prevented in the fallopian tube

3. A fertilized egg may be blocked from implanting in the uterus

4. Mucus around the cervix may become thicker and trap sperm from traveling to the fallopian tube

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Sources: Women's Capital Corp., Associated Press